CONCLUSION

With entry of the above Supplemental Amendment, it is respectfully submitted that the pending claims are in condition for allowance.

None of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application. The amendments are made solely to expedite prosecution.

The Examiner is invited to call Applicant's undersigned attorney at (312) 701-8979 for questions and to expedite prosecution.

Respectfully submitted,

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Complete Listing of All Claims in the Application
As of June 19, 2003

1.- 210. (Cancelled)

E1

211. (Currently Amended) A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel ~~or cream~~ composition ~~comprising~~ to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone, about 0.1% to about 5% (w/w) of at least one penetration enhancer, and about 0.1% to about 5% (w/w) of at least one gelling agent, ~~to a male subject~~ and

b) a pharmaceutical ~~useful for treating erectile dysfunction in the subject~~ selected from the group consisting of: sildenafil, pentoxyifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof,

wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction.

212. (Currently Amended) The method of claim 211, wherein the pharmaceutical comprises ~~at least one of:~~ sildenafil ~~citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, or phentolamine, or a combination, salt, or enantiomer thereof~~ in an amount of about 25 mg to about 100 mg.

213. (Currently Amended) The method of claim 211, wherein the pharmaceutical comprises ~~at least one of a phosphodiesterase inhibitor or a dopamine receptor agonist, or a combination, salt, or enantiomer thereof~~ apomorphine in an amount of about 1 mg to about 5 mg.

214. (Currently Amended) The method of claim ~~213~~ 211, wherein the ~~phosphodiesterase inhibitor is at least one of type III, type IV, or type V, and mixtures thereof~~ pharmaceutical comprises IC-351 (tadalafil) in an amount of about 5 mg to about 30 mg.

215. (Cancelled)

216. (Previously Added) The method of claim 211, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

217. (Currently Amended) The method of claim 211, wherein the composition comprises about ~~0.5% to about 10~~ 1.0% w/w of testosterone.

E1 Cont

218. (Cancelled)

219. (Currently Amended) The method of claim ~~218~~ 211, wherein the penetration enhancer is selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, ~~and terpenes~~ a terpene, and combinations of any of the foregoing.

220. (Previously Added) The method of claim 219, wherein the penetration enhancer is isopropyl myristate.

221. (Currently Amended) The method of claim ~~218~~ 211, wherein the gelling agent comprises polyacrylic acid.

222. (Currently Amended) The method of claim ~~218~~ 211, wherein the composition further comprises an alcohol ~~is~~ selected from the group consisting of: ethanol and isopropyl.

223. (Currently Amended) The method of claim ~~218~~ 211, wherein the composition further comprises ~~about 0.5% to about 10% testosterone; about 30% to about 98% alcohol; about 0.1% to about 5% penetration enhancer; and about 0.1% to about 5% gelling agent, wherein the percentages are weight to weight of the composition~~ from about 1% to about 5% (w/w) 0.1 N sodium hydroxide.

224. (Cancelled)

225. (Cancelled)

226. (Previously Added) The method of claim 211, wherein the composition and the pharmaceutical are components of a kit.

227. (Previously Added) The method of claim 211, wherein the subject is eugonadal or hypogonadal.

E'
Exit

228. (Cancelled)

229. (Previously Added) The method of claim 211, wherein the composition is administered to the subject in an amount suitable to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

230. (Cancelled)

231. (Previously Added) The method of claim 211, wherein the composition is administered at least once per day.

232. (Cancelled)

233. (Cancelled)

234. (Currently Amended) A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel ~~or cream~~ composition ~~comprising~~ to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone, about 0.1% to about 5% (w/w) of at least one penetration enhancer, and about 0.1% to about 5% (w/w) of at least one gelling agent, ~~to a male subject~~ and

b) a pharmaceutical useful for treating erectile dysfunction in the subject, wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction, ~~and~~

wherein the method is more effective in treating erectile dysfunction than a method comprising the administration of either the pharmaceutical or the composition alone.

235. (Currently Amended) The method of claim 234, wherein the pharmaceutical comprises at least one of: sildenafil ~~citrate~~, pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof.

E1 cont

236. (Previously Added) The method of claim 234, wherein the pharmaceutical comprises at least one of a phosphodiesterase inhibitor or a dopamine receptor agonist, or a combination, salt, or enantiomer thereof.

237. (Previously Added) The method of claim 236, wherein the phosphodiesterase inhibitor is at least one of type III, type IV, or type V, and mixtures thereof.

238. (Previously Added) The method of claim 237, wherein the phosphodiesterase inhibitor is type V.

239. (Previously Added) The method of claim 234, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

240. (Currently Amended) The method of claim 234, wherein the composition comprises about ~~0.5% to about 10~~ 1.0% w/w of testosterone.

241. (Currently Amended) The method of claim 234, wherein the ~~composition comprises testosterone, alcohol, a penetration enhancer, and a gelling agent~~ combination has a synergistic effect in treating erectile dysfunction.

242. (Currently Amended) The method of claim ~~241~~ 234, wherein the penetration enhancer is selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl

ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, ~~and terpenes~~ a terpene, and combinations of any of the foregoing.

243. (Previously Added) The method of claim 242, wherein the penetration enhancer is isopropyl myristate.

E1 Cont

244. (Previously Added) The method of claim 241, wherein the gelling agent comprises polyacrylic acid.

245. (Currently Amended) The method of claim ~~241~~ 234, wherein the composition further comprises an alcohol ~~is~~ selected from the group consisting of: ethanol and isopropyl.

246. (Currently Amended) The method of claim ~~241~~ 234, wherein the ~~composition comprises about 0.5% to about 10% testosterone; about 30% to about 98% alcohol; about 0.1% to about 5% penetration enhancer; and about 0.1% to about 5% gelling agent, wherein the percentages are weight to weight of the composition~~ pharmaceutical comprises sildenafil in an amount of about 25 mg to about 100 mg.

247. (Currently Amended) The method of claim ~~246~~ 234, wherein the composition further comprises about 1% to about 5% 0.1 N sodium hydroxide.

248. (Currently Amended) The method of claim ~~247~~ 234, wherein the ~~composition comprises:~~

~~a) about 0.5% to about 10% testosterone;~~

~~b) about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;~~

~~c) about 0.1% to about 5% penetration enhancer, selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide~~

~~dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, and terpenes;~~

~~d) about 1% to about 5% sodium hydroxide; and~~

~~e) about 0.1% to about 5% gelling agent;~~

~~wherein the percentages are weight to weight of the composition~~ pharmaceutical comprises apomorphine in an amount of about 1 mg to about 5 mg.

249. (Previously Added) The method of claim 234, wherein the composition and the pharmaceutical are components of a kit.

E1 Cont

250. (Previously Added) The method of claim 234, wherein the subject is eugonadal or hypogonadal.

251. (Currently Amended) The method of claim 234, ~~wherein the subject is a man, and the composition is administered to an area of skin selected from the group consisting of: arm, shoulder, abdomen, back, and thigh~~ pharmaceutical comprises IC-351 (tadalafil) in an amount of about 5 mg to about 30 mg.

252. (Previously Added) The method of claim 234, wherein the composition is administered to the subject in an amount suitable to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

253. (Cancelled)

254. (Previously Added) The method of claim 234, wherein the composition is administered at least once per day.

255.- 358. (Cancelled)

359. (Currently Amended) A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel ~~or cream~~ composition ~~comprising~~ to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone; about 0.1% to about 5% (w/w) of at least one penetration enhancer selected

from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, a terpene, and combinations of any of the foregoing; and about 0.1% to about 5% (w/w) of at least one gelling agent, ~~to a male subject~~ and

E 1 Cont

b) a pharmaceutical ~~useful for treating erectile dysfunction in the subject, wherein the pharmaceutical is~~ selected from the group consisting of: sildenafil, ~~citrate or~~ pentoxyifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof;

wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction, and

wherein the method is more effective in treating erectile dysfunction than a method comprising the administration of either the pharmaceutical or the composition alone.

360. (Previously Added) The method of claim 359, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

361. (Currently Amended) The method of claim 359, wherein the composition comprises about ~~0.5% to about 10~~ 1.0% w/w of testosterone.

362. (Cancelled)

363. (Previously Added) The method of claim 362, wherein the penetration enhancer is isopropyl myristate.

364. (Previously Added) The method of claim 359, wherein the gelling agent comprises polyacrylic acid.

365. (Currently Amended) The method of claim 359, wherein the composition further comprises an alcohol selected from the group consisting of: ethanol and isopropyl.

366. (Currently Amended) The method of claim 359, wherein the ~~composition comprises about 0.5% to about 10% testosterone; about 30% to about 98% alcohol; about 0.1% to about 5% penetration enhancer; and about 0.1% to about 5% gelling agent, wherein the percentages are weight to weight of the composition~~ combination has a synergistic effect in treating erectile dysfunction.

367. (Currently Amended) The method of claim ~~366~~ 359, wherein the composition further comprises from about 1% to about 5% (w/w) 0.1 N sodium hydroxide.

E1 Cont

368. (Cancelled)

369. (Previously Added) The method of claim 359, wherein the composition and the pharmaceutical are components of a kit.

370. (Previously Added) The method of claim 359, wherein the subject is eugonadal or hypogonadal.

371. (Cancelled)

372. (Previously Added) The method of claim 359, wherein the composition is administered to the subject in an amount suitable to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

373. (Currently Amended) The method of claim 359, wherein the ~~composition administered to the subject achieves a maximum serum testosterone concentration at about 16 hours to about 22 hours after administration of the composition~~ pharmaceutical comprises sildenafil in an amount of about 25 mg to about 100 mg.

374. (Previously Added) The method of claim 359, wherein the composition is administered at least once per day.

375. (Currently Amended) The method of claim ~~374~~ 359, wherein the ~~composition is administered to the subject for a sufficient number of days so as to achieve a~~

~~steady-state serum testosterone concentration~~ pharmaceutical comprises apomorphine in an amount of about 1 mg to about 5 mg.

E1 Cont'd

376. (Currently Amended) The method of claim ~~375~~ 359, wherein the ~~composition is administered to the subject for approximately 7 days~~ pharmaceutical comprises IC-351(tadalafil) in an amount of about 5 mg to about 30 mg.

377.-394. (Cancelled)